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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,330	10/22/2003	Istvan Boldogh	265.00390101	1384
26813	7590	10/25/2006	EXAMINER	
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/691,330	Applicant(s) BOLDOGH ET AL.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-6, 8 and 12-15 are pending.

Applicants' amendment filed August 17, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1 and 12 have been amended. Therefore, claims 1-6, 8 and 12-15 are examined.

### *Maintained Claim Rejections-Obviousness Type Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-6, 8 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 6,500,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates UV-irradiation is a major cause of oxidative stress in the cells and may induce apoptosis

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(Example 8; pages 28-29). This is obvious in view of claims 1-8 of the patent which disclose a method for modulating the oxidative stress level in a cell, the method comprising contacting the cell with an oxidative stress regulator under conditions effective to decrease the level of an oxidizing species in the cell in response to an oxidative stress, wherein the oxidative stress regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO: 1-34), an active analog of a constituent peptide of colostrinin (SEQ ID NO: 1-34) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for modulating the oxidative stress level in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof in response to apoptosis or an oxidative stress such as UV-irradiation, which is the same method step as encompassed by the two methods. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-8 of the patent are obvious variations of a method for inhibiting apoptosis or a method for modulating the oxidative stress level in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof in response to apoptosis or an oxidative stress.

*Response to Arguments*

Applicants indicate the Examiner is improperly using the teachings of the specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the Examiner has misinterpreted the teachings of the specification. Example 8 of the specification states that "[b]esides being a major cause of oxidative stress in the cells, UVB-irradiation induces apoptosis by a large number of related pathways such as enhanced Fas transcription and/or mRNA stability, induction of transcriptional factors via c-fos, c-jun, SAP-1 and nuclear factor kB gene expression" (page 29, lines 5-9 of the

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specification). The specification discloses that the induction of oxidative stress and the induction of apoptosis are mechanistically separate pathways within the cell, and are not obvious one over the other. Therefore, withdrawal of the rejection is requested (pages 5-7 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. While induction of oxidative stress by UVB-irradiation and the induction of apoptosis by UVB-irradiation are mechanistically separate pathways within the cell, the UVB-irradiation can cause both oxidative stress and apoptosis. Furthermore, the method for inhibiting apoptosis or protecting against DNA damage in a cell has the same method step (i.e., contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof in response to apoptosis or an oxidative stress) as the method for modulating the oxidative stress level in a cell, therefore, it would be expected that the treatment of cell with colostrinin, a constituent peptide of colostrinin or combination thereof produces the desired results (i.e., inhibiting apoptosis or protecting against DNA damage in a cell, or modulating the oxidative stress level in a cell).

3. Claims 1-6, 8 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U. S. Patent 6,903,068.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates colostrinin induces a variety of cytokines in leukocytes or modulates

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cytokine production (page 8, lines 11-15; page 22, lines 32-33; page 29, lines 24-30). This is obvious in view of claims 1-10 of the patent which disclose a method for inducing a cytokine or a method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO: 1-8 and 34), an active analog of a constituent peptide of colostrinin (SEQ ID NO: 1-8 and 34) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for inducing a cytokine in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof, which is the same method step as encompassed by the two methods. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-10 of the patent are obvious variations of a method for inhibiting apoptosis or a method for inducing a cytokine in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof.

*Response to Arguments*

Applicants indicate the Examiner is improperly using the teachings of the specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the present methods of claims 1-6, 8, and 12-15 are patentably distinct from the methods of claims 1-10 of U.S. Patent No. 6,903,068. Therefore, withdrawal of the rejection is requested (page 8 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. The specification of instant application teaches colostrinin induces a variety of cytokines in leukocytes or modulates cytokine production (page

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8, lines 11-15; page 22, lines 32-33; page 29, lines 24-30), thus colostrinin can induce a cytokine in a cell. Furthermore, the method for inhibiting apoptosis or protecting against DNA damage in a cell has the same method step (i.e., contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof) as the method for inducing a cytokine in a cell, therefore, it would be expected that the treatment of the cell with colostrinin, a constituent peptide of colostrinin or combination thereof produces the desired results (i.e., inhibiting apoptosis or protecting against DNA damage in a cell, or inducing a cytokine in a cell).

4. Claims 1-6, 8 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent 7,119,064 (previously US application no. 10/691,157). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates 4-HNE (4-hydroxynonenal) induce apoptosis (Example 7; page 28). This is obvious in view of claims 1-7 of the patent which disclose a method for modulating an intracellular signaling molecule in a cell such as reducing 4-hydroxynonenal (4HNE)-protein adduct formation, inhibiting 4HNE-mediated glutathione depleting, inhibiting 4HNE-induced activation of p53 protein, inhibiting 4HNE-induced activation of c-Jun NH2-terminal kinases, or a method for down regulating 4HNE-mediated oxidative damage associated with lipid peroxidation in a cell, the method comprising contacting

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the cell with an effective amount of a regulator, wherein the regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for modulating an intracellular signaling molecule in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof, which is the same method step as encompassed by the two methods. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-7 of the patent are obvious variations of a method for inhibiting apoptosis or a method for modulating an intracellular signaling molecule in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof.

*Response to Arguments*

Applicants indicate the Examiner is improperly using the teachings of the specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the present methods of claims 1-6, 8 and 12-15 are patentably distinct from the methods of claims 1-7 of U.S. Patent No. 7,119,064. Therefore, withdrawal of the rejection is requested (pages 9-10 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. The specification of instant application teaches 4-HNE (4-hydroxynonenal) induces apoptosis (Example 7, page 28), and colostrinin inhibits apoptosis in a cell. Furthermore, the method for inhibiting apoptosis or protecting against DNA damage in a cell has the same method step (i.e., contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof) as the method for modulating an intracellular signaling molecule in a cell, therefore, it would be expected that the



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treatment of the cell with colostrinin, a constituent peptide of colostrinin or combination thereof produces the desired results (i.e., inhibiting apoptosis or protecting against DNA damage in a cell, or modulating an intracellular signaling molecule in a cell).

### *Conclusions*

5. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner

 *primary* **CHIH-MIN KAM  
PATENT EXAMINER**

CMK

October 23, 2006